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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/950,071	Farwick et al.
Examiner	**Art Unit**
Christian L. Fronda	1652

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above, claim(s) *7-9, 23-25, and 27-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 10-22, and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☒ All b)☐ Some* c)☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)

16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18)☐ Interview Summary (PTO-413) Paper No(s). _____

19)☐ Notice of Informal Patent Application (PTO-152)

20)☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1-6, 10-22, and 26, in Paper No. 8 is acknowledged. The traversal is on the grounds that a search of all the claims would not constitute a serious burden and that Groups II-VII and Groups X-XII are classified in the same subclasses. This is not found persuasive for the reasons stated in the previous Office Action, specifically, each of the processes of II-VII and Groups X-XII are distinct both physically and functionally, require different process steps, reagents, and parameters, have different purposes, and produce different products. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-6, 10-22, and 26 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-6, 10-22, and 26 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Applicants disclose the nucleotide sequences of SEQ ID NO: 1 and the deduced amino acid sequence of the protein encoded by the nucleotide sequence of SEQ ID NO: 1 as the amino acid sequence of SEQ ID NO: 2. Applicants disclose that the protein of SEQ ID NO: 2 has the activity of the RodA cell division protein which is a generic asserted utility. The specification does not specifically disclose the specific function of the protein of SEQ ID NO: 2 or its relationship to any disease. It appears that the main utility of the nucleic acid and protein is to carry out further research to identify the biological function and possible diseases associated with the protein. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

Applicant is referred to the revised interim guidelines concerning compliance with 35 U.S.C. 101, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-6, 10-22, and 26 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above in the rejection of claims 1-6, 10-22, and 26 under 35 U.S.C. 101, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, the claims encompass any isolated polynucleotide which is at least 70%, 80%, or 90% identical to SEQ ID NO: 1. Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

While molecular biological techniques and genetic manipulation techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding the biological function, biological activity, or utility of polynucleotides which are at least 70%, 80%, or 90% identical to SEQ ID NO: 1 is lacking. Thus, searching for the biological function, biological activity, or utility of said polynucleotides is well outside the realm of routine experimentation and predictability in the art of success in determining the biological function, biological activity, or utility of said polynucleotides is extremely low.

The amount of experimentation to determine the biological function, biological activity, or utility of said polynucleotides is enormous and entails screening for a vast number of organisms for an organism that contains said polynucleotides and determining the biological function, biological activity, or utility of the polynucleotides. Alternatively, such experimentation entails deleting, adding, substituting, or combinations thereof nucleotides in SEQ ID NO: 1 to make a polynucleotide that is at least 70%, 80%, or 90% identical to SEQ ID NO: 1 and determining the biological function, biological activity, or utility of the polynucleotide.

Since routine experimentation in the art does not include screening or making vast numbers of polynucleotides which are at least 70%, 80%, or 90% identical to SEQ ID NO: 1, where the expectation of obtaining a desired biological function, biological activity, or utility is unpredictable, the Examiner finds that one skilled in the art would require additional guidance,

such as information regarding the structure and function relationship of the claimed polynucleotides. Without such a guidance, the experimentation left to those skilled in the art is undue.

7. Claims 1-6, 10-22, and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to all possible polynucleotides having at least 70%, 80%, 90% identity to SEQ ID NO: 1, all possible polynucleotides encoding a protein comprising the amino acid sequence of SEQ ID NO: 2, or all possible polynucleotides comprising SEQ ID NO: 1. The specification, however, only provides a single representative species encompassed by these claims: a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 1. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these polynucleotides by any identifying structural characteristics or properties for which no predictability of structure is apparent. The specification does not provide a written description of the amino acid sequence that is N-terminal or C-terminal to the amino acid sequence of SEQ ID NO: 2 or the nucleotide sequence that is 5' or 3' of SEQ ID NO: 1. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 2, 10, 18, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "RodA cell division protein" or "RodA protein" renders the claims indefinite because the specific activity of the claimed protein is not known and recited in the claims.

Claim Rejections - 35 U.S.C. § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Yum et al.

Claim 16 is anticipated by Yum et al. (Accession AB018544) since Yum et al. teach a polynucleotide sequence that comprises at least 15 contiguous nucleotides of the polynucleotide sequence of SEQ ID NO: 1 (see Alignment No. 1).

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

PONNATHAPU ACHUTAMURTHY
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